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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,898	10/26/2006	Ellen Jessouroun	NIH275.001NP2	9576

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,898	JESSOUROUN ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/1/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

3. The information disclosure statement filed on 9/1/2006 has been considered. An initialed copy is enclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lees, A US Patent No. 5849301 Date December 15, 1998 in view of Penney et al US Patent No. 5773007 Date June 30, 1998, and Peetermans et al US Patent No. 6756040 Date 6/29/2004 US Filing Date May 23, 2002.

Claims 1-14 are drawn to a method for preparing a conjugate vaccine, the method comprising: reacting a polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained;
reacting a protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained; reacting the aldehyde-activated polysaccharide with the hydrazine- activated protein at a pH of from about 5 to about 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained; and neutralizing unreacted aldehyde groups with acidic acid dihydrazide, whereby a conjugate vaccine capable of stimulating an immune response is obtained.

Lees A teaches a method for preparing a conjugate vaccine, the method comprising: reacting a polysaccharide with an oxidizing agent (sodium periodate), whereby a solution of an aldehyde-activated polysaccharide is obtained; reacting a protein with hydrazine at an acidic pH (see column 6 lines 65-67, column 7 lines 1-3, "reaction of hydrazides"), whereby a solution of a hydrazine-activated protein is obtained; whereby a conjugate is obtained; and neutralizing unreacted aldehyde groups with acidic acid dihydrazide, whereby a conjugate vaccine capable of stimulating an immune response is obtained, wherein the oxidizing agent comprises NaIO4 (see column 5 lines 27-32), wherein the solution of the aldehyde-activated polysaccharide is buffer exchanged with a HEPES buffer, wherein the solution of the aldehyde-activated polysaccharide is buffer exchanged to a pH of from about 7 to about 8 (column 11 lines

55-65), wherein the solution of the hydrazine-activated protein is buffer exchanged with a carbonate buffer (column 11 lines 55-65), wherein the solution of the hydrazine-activated protein is buffer exchanged to a pH of from about 10.0 to about 11.0, wherein a pH of the solution of the hydrazine-activated protein is raised to from about 7.0 to about 11 before the solution of the hydrazine-activated protein is buffer exchanged to a pH of from about 10.0 to about 11.0, whereby substantially all unreacted compounds and unconjugated polysaccharides are removed, yielding a purified conjugate vaccine, wherein the polysaccharide is selected from the group consisting of Meningococcal polysaccharides, Pneumococcus polysaccharides, Hemophilus influenzae type b polysaccharide, and group B Streptococcus polysaccharides, wherein the protein is selected from the group consisting of tetanus toxoid, diphtheria toxoid, and CRM197 (see column 9 lines 1-7), further comprising the step of adding saccharose as a stabilizer to the concentrated purified conjugate vaccine (see column 15), yielding a stabilized conjugate vaccine further comprising the step of concentrating the purified conjugate vaccine by tangential flow ultrafiltration (see column 11), yielding a concentrated purified conjugate vaccine, wherein the aldehyde-activated polysaccharide is reacted with the hydrazine-activated protein at a ratio of from about 1:1.6 to about 1:5 (see column 12 lines 50-57).

Lees et al does not teach a method step of reacting the aldehyde-activated polysaccharide with the hydrazine- activated protein at a pH of from about 5 to about 7 in the presence of sodium cyanoborohydride, further comprising the step of freeze drying the concentrated purified conjugate vaccine, yielding a dried conjugate vaccine.

Penney et al teach a method step of reacting the aldehyde-activated polysaccharide with the hydrazine- activated protein at a pH in the presence of sodium cyanoborohydride (see "Polysaccharide Conjugates")

Peetermans et al teach a method comprising the step of freeze drying the concentrated purified conjugate vaccine, yielding a dried conjugate vaccine (see claims and "Description).

As to claim 1, that recites "hydrazine dichloride". The reference teaches "hydrazine". Hydrazine dichloride is hydrazine in a salt form as evidenced A. E. Tutton

Nature 1891 No. 1105 Vol. 43 pgs. 205-210) therefore Lees anticipates "hydrazine dichloride".

It would have been prima facie obvious at the time the invention was made to incorporate a method step of reacting the aldehyde-activated polysaccharide with the hydrazine-activated protein at a pH in the presence of sodium cyanoborohydride as taught by Penney et al into the method as taught by Lees because both teach a method of preparing a conjugate vaccine. It would also have been prima facie obvious at the time the invention was made to incorporate a of freeze drying the concentrated purified conjugate vaccine, yielding a dried conjugate vaccine as taught by Peetermans et al into the method as taught by Lees because both teach a method of preparing a conjugate vaccine.

As to the limitation of claim 1 wherein the hydrazine-activated protein at a ph 5 to about 7. The prior does not does not teach the specific range of ph as claimed. The amount of a specific ph in a method is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Status of the Claims

No claims are allowed.

Claims 1-14 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER